

REMARKS

Claims 54-63 and 65-103 are pending in the application. All claims were rejected in the Office Action of October 10, 2007.

I. Specification

The Office Action states that the specification is objected to because page 27, first paragraph, “contains sections of text that have been rendered unreadable.” Applicants do not understand this objection, and submit that page 27, first paragraph, of the specification is clear and readable, so that the objection should be reconsidered and withdrawn. If this objection is not withdrawn, Applicants respectfully request identification of specific sections of text and explanation of why they are “unreadable.”

II. Claim Rejection Under 35 U.S.C. § 112, 1st Paragraph – Enablement

Claims 54-63 and 65-103 were rejected under § 112, first paragraph, as lacking enablement because the specification allegedly does not provide sufficient support for selection of surfactants and lipids suitable for use in the claimed methods. In particular, the Office Action expresses concern that although the specification describes phosphatidylcholines as useful in the claimed penetrants, Applicants distinguished a certain didecanoyl-L- α -phosphatidylcholine absorption enhancer disclosed in the previously-cited Drejer reference as unlikely to function as claimed. Applicants respectfully traverse this rejection.

The specification and claims provide ample information on how to prepare suitable penetrant compositions with lipids and surfactants as claimed. As an initial matter, independent claims 54 and 100 explicitly define in functional terms the properties of a suitable penetrant, namely, a minute fluid droplet with a coating of at least two substances that differ by at least a factor of 10 in solubility, the substances forming aggregates with specified diameter limitations, the more soluble substance solubilizing the droplet, and/or the coated droplet having a particular elastic deformation energy as claimed. This functional claim language ensures that the claims do not read on inoperative embodiments. In any case, even a claim encompassing some inoperative embodiments is not invalid for lack of enablement if one skilled in the art could determine the operative embodiments without undue experimentation. *See* MPEP 2164.08(b), citing *Atlas Powder Co. v. E.I. du Pont de Nemours & Co.*, 750 F.2d 1569, 1577 (Fed. Cir. 1984).

The specification at pages 26-28 lists various lipids and surfactants suitable for use in the claimed penetrants. The Office Action suggests that this list may include some inoperative substances. Again this does not mean that undue experimentation would be required for one of ordinary skill in the art to prepare a penetrant as claimed, because sufficient guidance is provided in the specification and claims to allow selection of suitable materials. Indeed, in addition to the substantial guidance within the claims themselves, the specification exemplifies the preparation of penetrants containing phospholipids (*e.g.*, phosphatidylcholine) and surfactants (*e.g.*, cholate or polysorbate). *See, e.g.*, page 40, second and third paragraphs, and subsequent Examples. Moreover, the specification cites and/or incorporates by reference various publications providing one skilled in the art with further information regarding suitable penetrants and their preparation and properties. *See* page 13, fourth and fifth paragraphs. A description of how to convert conventional lipid vesicles into penetrants as claimed is also provided at page 16, first paragraph.

One of ordinary skill in the art would only have to follow this disclosure, and thus would require no undue experimentation, to make a penetrant composition with lipids and surfactants as claimed. The Office Action implies that one skilled in the art might have to experiment with a number of lipids or surfactants to identify materials that function as claimed, because Applicants identified a material that would not be expected to work. However, even if this were the case, an extended amount of experimentation is not undue if sufficient guidance as to the desired direction, procedures and results is provided in the specification and claims, as it is in the above-identified passages of the present application. *See* MPEP 2164.06, citing *In re Colianni*, 561 F.2d 220, 224, (CCPA 1977); *In re Wands*, 858 F.2d 731, 737 (Fed. Cir. 1988).

In addition, the Declaration of Dr. Gregor Cevc submitted on June 28, 2007 exemplifies how one skilled in the art could readily evaluate the operative embodiments according to the functional characteristics identified in the claims and specification. *See, e.g.*, ¶¶ 11-12 and 15. For example, one skilled in the art would readily appreciate, as explained in paragraph 11 of the declaration, that the particular phosphatidylcholine disclosed by Drejer does not “form large bilayer vesicle aggregates, as is requested in the Application, but rather self-assembles into small aggregates in micellar form, owing to is [*sic*] too high water solubility.”

In sum, the extensive guidance provided in the specification and claims ensures that a person of ordinary skill in the art would readily be able to prepare suitable penetrants as claimed

without undue experimentation. Accordingly, Applicants respectfully submit that the present enablement rejection should be reconsidered and withdrawn.

III. Claim Rejection Under 35 U.S.C. § 112, 1st Paragraph – Written Description

Claims 54-63 and 65-103 were rejected under § 112, first paragraph, for allegedly lacking sufficient written description. The Office Action contends that the specification does not sufficiently describe distinguishing characteristics to convey possession of the genus of lipids and surfactants that will function in the claimed methods. Applicants respectfully traverse this rejection.

Written description for a claimed genus is satisfied by providing sufficient description of a representative number of species within the genus, and/or identifying characteristics such as structure, physical properties, chemical properties, and/or functional characteristics. *See* MPEP 2163, citing *Regents of the University of California v. Eli Lilly*, 119 F.3d 1559, 1568 (Fed. Cir. 1997), *cert. denied*, 523 U.S. 1089 (1998). The Office Action asserts that the only factor present in the claims is the recitation that the penetrant includes a lipid and a surfactant or more soluble form of the lipid. Applicants respectfully disagree. As an initial matter, the recitation of lipids and surfactants itself conveys a discrete group of compounds having common structural elements, physical and chemical properties that are well-understood by those skilled in the art. Moreover, independent claims 54 and 100 additionally set forth a detailed group of functional characteristics that clearly describe multiple features of the lipid and surfactant substances that form a suitable penetrant. In particular, the claims recite a minute fluid droplet with a coating of at least two substances that differ by at least a factor of 10 in solubility, the substances forming aggregates with specified diameter limitations, the more soluble substance solubilizing the droplet, and/or the coated droplet having a particular elastic deformation energy as claimed. These features are also identified in the body of the specification, for example, in the paragraph bridging pages 12-13.

In addition to the description in the claims themselves, the specification provides ample support for the claimed penetrant including a lipid and a surfactant or more soluble form of the lipid. The specification at pages 26-28 lists various lipids and surfactants suitable for use in the claimed penetrants, identifying these materials by chemical names and/or structures. The

specification also exemplifies the preparation of penetrants containing useful species of materials, namely, phospholipids (*e.g.*, phosphatidylcholine) and surfactants (*e.g.*, cholate or polysorbate). *See, e.g.*, page 40, second and third paragraphs, and subsequent Examples. Moreover, the specification cites and/or incorporates by reference various publications providing one skilled in the art with further information regarding suitable penetrants and their preparation and properties. *See* page 13, fourth and fifth paragraphs. A description of how to convert conventional lipid vesicles into penetrants as claimed is also provided at page 16, first paragraph.

The Office Action expresses concern that although the specification describes phosphatidylcholines as useful in the claimed penetrants, Applicants distinguished a certain didecanoyl-L-alpha-phosphatidylcholine absorption enhancer disclosed in the previously-cited Drejer reference as unlikely to function as claimed. However, the fact that a category of lipids generally described as useful includes an inoperative material does not render Applicants' written description insufficient. To the contrary, one skilled in the art would understand that in addition to listing categories of potentially useful materials, Applicants further defined the genus of useful lipids and surfactants based on functional characteristics. These characteristics are set forth in the specification and claims, and are demonstrated in the working Examples, which also exemplify particular combinations of materials that form conventional liposomes or micelles instead of penetrants as claimed. The Declaration of Dr. Gregor Cevc submitted on June 28, 2007 also provides examples of the types of observations that one skilled in the art would readily make to appreciate which materials do or do not exhibit the claimed functional characteristics. *See, e.g.*, ¶¶ 11-12 and 15. Thus, based on the full disclosure in the specification and claims, one skilled in the art would appreciate that Applicants had possession of the claimed subject matter at the time the application was filed.

In sum, the specification and claims clearly provide sufficient written description, by identifying many types of useful materials by name/structure, describing functional characteristics required for the materials to operate as claimed, and providing working examples demonstrating particular species of compositions as claimed, as well as comparative compositions. Accordingly, Applicants respectfully submit that the present written description rejection should be reconsidered and withdrawn.

IV. Conclusion

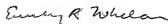
In view of the arguments set forth above, Applicants respectfully submit that the objections and rejections contained in the Office Action mailed on October 10, 2007 have been overcome, and that the pending claims are in condition for allowance.

No fees are believed to be due in connection with this correspondence. However, please charge any payments due or credit any overpayments to our Deposit Account No. 08-0219.

The Examiner is encouraged to telephone the undersigned at the number listed below in order to expedite the prosecution of this application.

Respectfully submitted,

Dated: 1/9/08


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